II. REMARKS

A. Status of the Claims

Claims 6 and 24 have been amended without prejudice. Support for these amendments can be found, e.g., on page 18, lines 4-6, and on page 9, lines 10-22, both of the original specification as filed.

Claims 1-5, 9-12 and 17-23 were previously cancelled without prejudice.

Claims 6-7, 13-16 and 24-30 are pending.

Applicants respectfully submit that no new matter has been added by virtue of this amendment.

B. Claim rejection under 35 U.S.C. §103

In the Office Action, claims 6-8, 13-16, and 24-30 were rejected under 35 U.S.C. §103(a) over Goldie et al. (U.S. 4,844,909). In response to Applicants' argument that Goldie fails to recognize "the art recognized problem that dissolution release profiles change on ageing," the Examiner stated that "the features upon which applicant relies are not recited in the present claims."

In response, Applicants submit that independent claims 6 and 24 have been amended without prejudice to recite in part that a controlled-release formulation utilized in the methods of claim 6 and 24 comprises "a tablet overcoated with a cured stabilized coating derived from an aqueous dispersion of a hydrophobic polymer such that the tablet attains a dissolution profile which is substantially unaffected by exposure to storage conditions of at least one month at a temperature of 40°C and a relative humidity of 75%." (emphasis added).

Applicants respectfully submit that the Goldie reference fails to teach or suggest a hydromorphone formulation comprising "a tablet overcoated with a cured stabilized coating derived from an aqueous dispersion of a hydrophobic polymer such that the tablet attains a dissolution profile which is substantially unaffected by exposure to storage conditions of at least one month at a temperature of 40°C and a relative humidity of 75%," as recited in independent claims 6 and 24.

Applicants submit that, as stated in the response filed June 26, 2007, the Goldie reference fails to recognize the art recognized problem that dissolution release profiles change on ageing, which has been overcome in one of the embodiments of the present invention. See, e.g., page 16, line 21 to page 18, line 24, of the present specification as filed.

Accordingly, Applicants submit that the Goldie reference does not render obvious the methods of claims 6 and 24 utilizing a hydromorphone controlled-release formulation comprising a tablet overcoated with a cured stabilized coating derived from an aqueous dispersion of a hydrophobic polymer "such that the tablet attains a dissolution profile which is substantially unaffected by exposure to storage conditions of at least one month at a temperature of 40°C and a relative humidity of 75%" as recited in these claims. Therefore, Applicants respectfully request withdrawal of the obviousness rejection over the Goldie reference.

III. CONCLUSION

An early and favorable action on the merits is earnestly solicited. The Examiner is specifically authorized to contact the undersigned by telephone in the event a telephone interview would advance the prosecution of the application.

Respectfully submitted,
DAVIDSON, DAVIDSON & KAPPEL, LLC

By: _____
Oleg Joselevich
Reg. No. 56,963

Davidson, Davidson & Kappel, LLC
485 Seventh Avenue, 14th Floor
New York, New York 10018
(212) 736-1940